In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 12-673V
(not to be published)

KATHLEEN J. AUCH, Petitioner,	*	Special Master Corcoran
v.	*	Filed: January 13, 2017
SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	*	Decision; Influenza ("Flu") Vaccine; Polyneuropathic Injury; Onset of Symptoms; EMG Testing.

Richard Gage, Richard Gage P.C., Cheyenne, WY, for Petitioner.

Alexis B. Babcock, U.S. Dep't of Justice, Washington, DC, for Respondent.

DECISION DENYING ENTITLEMENT[1]

On October 4, 2012, Kathleen Auch filed a petition seeking compensation under the National Vaccine Injury Compensation Program (the "Vaccine Program"),[2] alleging that she experienced a generalized polyneuropathic injury after receiving the influenza ("flu") vaccine on October 6, 2009. Petition ("Pet.") (ECF No. 1) at 2.

An entitlement hearing was held in this matter on August 24, 2016, in Omaha, Nebraska. After considering the record as a whole, and for the reasons explained below, I find that Petitioner

[1] Although I am not designating this as a decision "to be published," because it contains a reasoned explanation for my action in this case it will nevertheless be posted on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). As provided by 42 U.S.C § 300aa-12(d)(4)(B), however, the parties may object to the decision's inclusion of certain kinds of confidential information. To do so, Vaccine Rule 18(b) permits each party fourteen (14) days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the entire decision will be available to the public. *Id.*

[2] The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (codified as amended at 42 U.S.C. § 300aa-10 through 34 (2012)).

has failed to carry her burden establishing causation, and therefore has not demonstrated entitlement to compensation under the Vaccine Program.

I. FACTUAL BACKGROUND

The record in this case consists of Ms. Auch's medical records, the testimony of two experts and three fact witnesses, and medical or scientific literature submitted by the parties in support of their respective positions. I have reviewed the entire record as required by the Vaccine Act.

A. *October 2009 Flu Vaccine and Initial Alleged Reactions*

Ms. Auch was 50 years old at the time of vaccination and had a medical history significant for fibromyalgia, depression, and anxiety. Petitioner's Exhibit ("Pet'r's Ex.") 1 at 7. Petitioner received the flu vaccine on October 6, 2009. At that time, she worked at a credit card call center in Yankton, South Dakota. Tr. at 26-27. Ms. Auch recounted that her employer had encouraged employees to receive the flu vaccine, so she did sometime that afternoon. *Id.* at 26, 56. She had not eaten much that day leading up to the vaccination. *Id*. at 56.

Petitioner reported that she experienced an immediate reaction to the vaccine, with her vision becoming blurry. Pet'r's Ex. 2 pt. 2 at 49. She went that same day to the emergency room in Yankton at the Avera McKennan Hospital. *Id*. The EMS notes from this visit state that Ms. Auch had collapsed at work after receiving the flu vaccine. Pet'r's Ex. 4 at 7. At the emergency room, Petitioner testified, her limbs were functioning but she felt very weak. Tr. at 29. The contemporaneous records confirm that she informed treaters at the time that she felt dizzy, weak, and generally "weird," although they provide no medical diagnosis for her reported symptoms. Pet'r's Ex. 2 pt. 2 at 47; Pet'r's Ex. 4 at 7.

Ms. Auch was thereafter referred to Dr. Susan Fanta at Avera McKennan with the aim of obtaining a diagnosis for her symptoms. Pet'r's Ex. 2 pt. 2 at 49. Dr. Fanta's records reflect Petitioner's complaints of feeling "funny" in the head and Petitioner's descriptions of having "spells." *Id*. Petitioner specifically reported that for the few months before the flu vaccination, she had been experiencing an "inside tremulousness sensation lasting several minutes, several times a day." *Id*. The notes also state that Ms. Auch reported that her daughter had at the time been experiencing flu-like symptoms, prompting Dr. Fanta to suggest that Petitioner's reaction might be a type of "prodromal symptomatology." *Id.* at 50. Ultimately, Ms. Auch declined hospital admission and was instead given a liter of saline before being discharged, with no proposed medical explanation for her post-vaccination symptoms. *Id.*

Three days later, on October 9, 2009, Ms. Auch saw Dr. Fanta for a follow-up examination. Pet'r's Ex. 3 at 12. Petitioner reported that she felt better but was still experiencing weakness. *Id*.

Petitioner also told Dr. Fanta that she had experienced similar dizziness to a lesser degree after receiving flu vaccines in the past, and Dr. Fanta therefore speculated that the sudden weakness could be related to the flu vaccine. *Id*. However, a systems review and limited testing again revealed no identifiable problems with Petitioner, and the cause of her symptoms remained unspecified. *Id.*

Petitioner returned to the emergency room on October 13, 2009 – a week after receiving the flu vaccine. Pet'r's Ex. 2 pt. 2 at 42. At hearing, Petitioner testified that in the time between this visit and her immediate post-vaccination ER visit, she had stayed home to rest but finally opted to go to work on the 13th. Tr. at 32. Upon arrival at her job, however, she began feeling ill and was shaking and trembling, so she asked a friend to take her to the emergency room. *Id.* at 32-33. Ms. Auch reported feeling as if she could not walk and specifically described her symptoms as similar to what she had experienced on her October 6th ER visit (although she is also recorded as having told initial treaters that her trembling symptoms had been recurring for a month, which would place their onset before receipt of the flu vaccine). Pet'r's Ex. 3 at 11; Pet'r's Ex. 2 pt. 2 at 37. An initial examination (consistent with prior exams) again revealed no identifiable problems, and in particular noted no focal neurologic findings. Pet'r's Ex. 3 at 11. However, the intake impressions noted (consistent with Dr. Fanta's prior speculation) that Ms. Auch may have been experiencing an allergic reaction to the flu vaccine. Pet'r's Ex. 2 pt. 2 at 42, 44; Pet'r's Ex. 3 at 11. Her potassium was also deemed low. Pet'r's Ex. 2 pt. 2 at 37.

Ms. Auch was subsequently admitted to the hospital overnight for treatment of her claimed symptoms and observation. Pet'r's Ex. 2 pt. 2 at 44. Upon admission, she was given Solu-Medrol,[3] an anti-inflammatory glucocorticoid used to treat pain and swelling that occurs with arthritis and other joint disorders.[4] *Id.* The next day, the attending physician, Dr. Dori Bigner, performed a thorough review of symptoms aimed at finding an explanation for Petitioner's ongoing symptoms. *See generally* Pet'r's Ex. 2 pt. 2 at 38-41. Her neurologic examination again revealed nothing notable that could explain her symptoms, although no imaging diagnostics were performed. *Id.* at 39. Dr. Fanta (who also saw Petitioner on October 14th) observed that Petitioner displayed focal weakness primarily in the lower, rather than upper, extremities and that she had weakness in her quadriceps and lower legs bilaterally. *Id.* at 45. The differential diagnosis included Guillain-Barré syndrome ("GBS") versus an unspecified myositis (which was deemed possibly linked to a prior viral infection Petitioner reported from August), and it was proposed that Ms. Auch obtain a

[3] Solu-Medrol is a trademark name for a preparation of methylprednisolone sodium succinate. *Dorland's Medical Dictionary* 1731 (32nd ed. 2012) (hereinafter *Dorland's*). Methylprednisolone sodium succinate is a synthetic glucocorticoid, administered by intramuscular or intravenous injection, and is used in replacement therapy for adrenocortical insufficiency and as an anti-inflammatory and immunosupressant. *Id.* at 1154. It is chiefly used for the rapid achievement of high blood levels of methylprednisolone in short-term emergency treatment. *Id.*

[4] It does not appear from the filed medical records (particularly those specifically recording medications that Ms. Auch received while hospitalized) that Ms. Auch continued to receive Solu-Medrol, or any other corticosteroid, after the first day of her admission to the hospital following her October 13, 2009, ER visit. *See* Pet'r's Ex. 2 pt. 1 at 49-55.

consultation with the neurology department to evaluate whether a lumbar puncture or electromyography ("EMG") test[5] was necessary. *Id.* at 40.

Petitioner remained an in-patient for the next five days at Avera McKennan Hospital while she obtained her neurology evaluation. *See generally* Pet'r's Ex. 2 pt. 1 at 1-5. During this time, she underwent a number of tests, including a brain MRI that revealed no evidence of demyelinating disease, a cervical spine MRI which showed a congenitally small cervical spinal canal, and an echocardiogram, which was normal. *Id.* at 1. She also underwent a neurologic diagnostic lab test which suggested possible postural orthostatic tachycardia syndrome ("POTS"),[6] though it was noted that Petitioner did not exhibit the typical findings often seen with this disorder. *Id*. Petitioner was started on Florinef[7] to help any symptoms that might be due to autonomic dysfunction. *Id.* at 2. Dr. Todd Zimprich, the neurologist who reviewed the test results suggestive of a possible POTS diagnosis, noted that there was no convincing evidence of a "more diffuse autonomic disorder." *Id.* at 9.

The contemporaneous records also reveal that on October 15, 2009, during Petitioner's five-day in-patient evaluation at Avera, an EMG was performed. The medical records and notes regarding the EMG test reinforced Dr. Zimprich's original opinion that the test results were "unremarkable," in that they showed "no convincing evidence of polyradiculopathy/polyradiculoneuropathy." Pet'r's Ex. 2 pt. 1 at 2; Pet'r's Ex. 60 at 1. Dr. Zimprich's records interpreted these first EMG results as somewhat unreliable due to Petitioner's poor tolerance for the testing itself. Pet'r's Ex. 60 at 1. Nevertheless, he found no convincing evidence of any polyradiculoneuropathies, plexopathies, or mononeuropathies affecting the upper and lower extremities, as well as no evidence of any other myogenic disorder. *Id.*

A handwritten addendum to the original medical record from this visit, prepared in December 2016 by one of Ms. Auch's former treaters and only recently filed in this action,[8]

[5] EMG is a diagnostic procedure to assess the health of muscles and the nerve cells that control them (motor neurons). *See Dorland's* at 602.

[6] POTS is made up of symptoms that sometimes occur when a person assumes an upright position, including tachycardia, tremulousness, light-headedness, sweating, and hyperventilation. *Dorland's* at 1844. The etiology is uncertain. *Id.*

[7] Florinef is the trademark name for fludrocortisone acetate, which is the acetate salt of a synthetic steroid with potent mineralocorticoid and high glucocorticoid activity, used in replacement therapy for primary or secondary adrenocortical insufficiency in different treatments and is administered orally. *Dorland's* at 718-19.

[8] At hearing, it was revealed that Petitioner had never obtained a copy of the actual EMG results, and thus the doctor's notes referencing the fact that an EMG had been performed and characterizing its results as unremarkable were the only evidence of its findings. Pet'r's Ex. 2 pt. 1 at 2; Tr. at 131. After trial, I asked Petitioner to produce a copy of the actual EMG result**s** if possible. Tr. at 226-27. Initially, Petitioner represented that she still could not obtain the EMG results. *See* Status Report, dated October 13, 2016 (ECF No. 84). Then, on December 29, 2016, Petitioner unexpectedly filed two documents: a handwritten addendum to Dr. Bigner's record from Petitioner's October 2009

explains that while Petitioner's EMG test results showing mild neuropathy in the wrist would normally suggest carpal tunnel syndrome, Dr. Zimprich found it more likely to be a false result due to technical factors, rather than evidence of an actual underlying neuromuscular disease. Pet'r's Ex. 59 at 5. The addendum also states that the EMG test was done in conjunction with other testing that revealed some evidence of POTS, leading to the ultimate POTS diagnosis on discharge. *Id.*

During this stay, Petitioner also received non-steroidal anti-inflammatory drugs, but was not given additional doses of Solu-Medrol or any other steroids. Pet'r's Ex. 2 pt. 1 at 47-55. A Lyrica trial was recommended (Pet'r's Ex. 2 pt. 1 at 45, 54), in addition to the Cymbalta she was already prescribed for depression. Pet'r's Ex. 2 pt. 1 at 46.

Upon discharge, Ms. Auch's treaters still could not identify the etiology of her symptoms. POTS was identified as the most likely diagnosis, however. Pet'r's Ex. 2 pt. 1 at 2. It was recommended that Ms. Auch continue treatment with Dr. Fanta, but also that she possibly obtain a POTS evaluation at the Mayo Clinic in Rochester, Minnesota. *Id.* at 4. Petitioner again repeated her concerns that her illness might be related to her October 6th flu vaccination, and although her treaters did not put much stock in the assertion, they encouraged her to report her symptoms to the CDC Vaccine Adverse Events Reporting System[9] website. *Id.* at 3. They also allowed for the possibility that Petitioner's autonomic instability might have been exacerbated by her anxiety. *Id*.

Two days after discharge, on October 21, 2009, an ambulance took Petitioner from her home to Avera Sacred Heart Emergency Room in Yankton for her third ER visit that month. Pet'r's Ex. 4 at 2. At hearing, Petitioner recalled feeling funny again and that she was now unable to move. Tr. at 40. She also testified that she "had all this pain and numbness and stuff in [her] legs and [her] hands were numb." *Id.* Petitioner specifically noted at hearing that she was in pain at this time – although the contemporaneous record reflects that Petitioner denied such pain when asked by the emergency responders. Pet'r's Ex. 4 at 2. Petitioner relayed to the EMS responders that she had been diagnosed with POTS and that a treater had suggested that her symptoms might be linked to GBS. *Id.* at 1-2. The responder's notes stated that Petitioner might be experiencing a "debatable" flu shot reaction. *Id.* at 4.

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evaluation at Avera McKennan and dated December 22, 2016, and the actual EMG results along with Dr. Zimprich's impressions. ECF No. 89 (Pet'r's Exs. 59 and 60).

[9] VAERS is a national vaccine safety surveillance program co-sponsored by the Centers for Disease Control and Prevention and the Food and Drug Administration, and allows individuals who believe they may have experienced a vaccine reaction to make a report of the incident. *See* https://vaers.hhs.gov/index (last visited Dec. 28, 2016). Because it is a passive reporting system, VAERS database findings that a number of individuals have complained of a supposed adverse effect from a particular vaccine does not imply causation, but such evidence can still be used as a means to find potential signals of causation.

Once Petitioner reached the ER, she characterized the incident as "another spell," repeating her claim that she could not walk or feel her legs, which felt numb and tingly. Pet'r's Ex. 18 at 1-3. However, she noted that she felt a bit better by the time she reached the hospital, and in fact was able to walk after being seen by a treater. *Id.* at 1-2. The doctor's impression was that she had "transient" syndrome, which included numbness, tingling, and partial paralysis of her lower extremities. *Id*. The ER treater proposed that the symptoms could be stress-related, but he lacked the expertise to rule out a more ominous type of autonomic nerve dysfunction or demyelinating disorder and felt that he could not further assist her since her reported symptoms had dissipated. *Id.* Dr. Robert Neumayr (who also served as an expert in this case) noted in an October 22, 2009, treatment record that the source of Ms. Auch's problems was largely unclear (and specifically that there were no focal neurologic findings), but that they dated from her receipt of the flu vaccine. Pet'r's Ex. 3 at 9.

B. *Subsequent Treatment through the End of 2009*

Petitioner obtained at-home treatment with Avera Sacred Heart Home Care from October 24, 2009, to November 4, 2009. During this time period, Ms. Auch utilized a walker and still experienced "spells" after walking for extending periods of time. Pet'r's Ex. 5 at 1. The Home Care specialist's notes specifically reveal that Petitioner had coordination difficulty, as well as a slow and unsteady gait pattern. *Id.* at 1, 37. However, by the end of the treatment, Petitioner stated that she was feeling "improved" every day and did not want to use her walker anymore. *Id.* at 14.

Petitioner was seen for follow-up visits at Yankton Medical Clinic on October 22, 2009, and October 30, 2009. Pet'r's Ex. 3 at 8-9. Dr. Fanta noted that Petitioner had received an apparent diagnosis of POTS, but admitted that she lacked the expertise with autonomic disorders to confirm the accuracy of the diagnosis, again stressing the need to seek POTS-specific treatment at a proper care center (by this point, the Mayo Clinic had reportedly declined to see Ms. Auch, despite the recommendation at her prior hospitalization discharge that she obtain a POTS evaluation there). *Id.* at 8. Dr. Fanta's notes also stated that Dr. Zimprich, who had performed the neurological testing on Petitioner during her hospital admission earlier that month, did not ask to see Petitioner for any follow-up. *Id*. Petitioner continued to report periods of weakness to the point of hardly functioning, however. *Id*.

Petitioner was seen again by Dr. Fanta on November 16, 2009. Pet'r's Ex. 3 at 3. Dr. Fanta now stated that Ms. Auch (who remained "functionally limited" in light of her persistent symptoms) had "probable" POTS, given that Petitioner's symptoms were fairly consistent with that condition. *Id.* at 3-4. Dr. Fanta also stated that Petitioner's dyspnea[10] was concerning, and she wanted a cardiologist to examine Petitioner. *Id.* at 4. On November 17, 2009, Petitioner was seen for a cardiac consultation at Yankton Medical Clinic. *Id.* at 1. A dobutamine stress echo test was

[10] Dyspnea is defined as breathlessness or shortness of breath. *Dorland's* at 582.

performed, and the notes discussing the results reveal that Petitioner experienced hyperventilation, which "caused reproduction of symptoms of numbness and tingling in her feet and arms" along with weakness. *Id.* at 1-2. The treater responsible for this testing proposed that these symptoms were likely "induced" by the hyperventilation. *Id*.

Later that same month, Petitioner was seen at the CentraCare Health Center in St. Cloud, Minnesota, for an assessment relating to POTS and/or other autonomic problems. Pet'r's Ex. 8 at 3. Dr. David Benditt, the treater who performed the assessment, noted his suspicion that the prior POTS diagnosis was a false positive, especially because additional attempts to reproduce the earlier results supportive of the diagnosis from her October hospitalization had failed, and because Petitioner was in an unstable state at the time of diagnosis due to her concomitant sickness. *Id.* at 4, 6. Dr. Benditt's notes further reflect that by this point, Ms. Auch's parasthesias were declining, and Petitioner was becoming less limited by the severity of her reported symptoms. *Id.* at 4. His examination also revealed no evidence of any ongoing inflammatory disease. *Id.* at 6. Dr. Benditt proposed that Petitioner might have suffered from a hypersensitivity reaction to the flu vaccine, which might have in turn triggered a sensory neuropathy resulting in parasthesias in the periphery. *Id.* Regardless, he predicted that Ms. Auch would soon be able to again live a productive life.

C. *Treatment of Other Illnesses in 2010*

Petitioner continued to be seen for various complaints over the next year – although the records reveal a cessation, for several months, in complaints of neuropathic symptoms of the sort she alleges to have experienced in October and November 2009. Thus, in March 2010, she was seen at Yankton Medical Clinic for abdominal pain and a CT scan was ordered. Pet'r's Ex. 12 pt. 2 at 44. These records make no reference to either Ms. Auch's October and November 2009 symptoms or vaccination, and her presenting symptoms were otherwise treated as if unconnected. She was next seen for a follow-up on April 29, 2010, regarding possible diverticulitis. Pet'r's Ex. 12 pt. 2 at 40. The records from this visit referenced her visits to the doctor earlier in 2010, but otherwise pertained only to her then-stated reason for seeking medical intervention, and thus did not reference her fall 2009 symptoms. *Id.* (Petitioner "offers no other concerns or complaints at this time").

Two months passed without Ms. Auch seeking any medical treatment. Then, in June 2010, Petitioner went back to the Yankton Clinic for treatment of her ongoing depression. Pet'r's Ex. 12 pt. 2 at 34-35. At this time, Petitioner discussed her antidepressant regime and the fact that she often experienced a variety of emotional symptoms connected with her depression. *Id.* As with her doctor's visits for treatment of her diverticulitis, however, Ms. Auch made no mention at all of her prior, allegedly vaccine-related, symptoms. By this point, Ms. Auch was again working – now as a home care service provider to handicapped individuals. Tr. at 76-77.

D. *Polyneuropathy Diagnosis in 2010*

Toward the end of the summer of 2010, Ms. Auch experienced neuropathic symptoms severe enough to compel her to seek treatment. Thus, on August 2, 2010, she returned again to the Yankton Medical Clinic, where she was seen by Dr. Terrance Pederson. Pet'r's Ex. 12 pt. 2 at 32. Petitioner reported that she had a lot of burning pain in both of her feet and described these symptoms as "something new here in the last few days." *Id*. She did not link these to her symptoms that she had been seen for previously in October 2009, nor did she even make mention of them; by contrast, she compared the symptoms she was experiencing to her fibromyalgia. *Id.* Ms. Auch was prescribed medication for her pain, and it was recommended that she pursue a neurologic consultation to evaluate if she was suffering from some kind of peripheral neuropathy. *Id.*

On August 4, 2010, Petitioner was seen by a neurologist, Dr. Jugal Raval, to whom she now reported (and contrary to the August 2nd record) that the burning pain in her feet had been occurring for the last couple of months. Pet'r's Ex. 12 pt. 2 at 28. She also informed Dr. Raval that she had received a flu shot "three years ago," and that she was unable to walk for almost three months after the vaccination. *Id*. Her history of depression and fibromyalgia were also recounted. *Id.*

Dr. Raval conducted an examination of Ms. Auch. The neurologic component of the examination (including tests of motor function and reflexes) was normal, with the exception of the sensory examination, which revealed decreased sensation in glove and stocking distribution. Pet'r's Ex. 12 pt. 2 at 29. Dr. Raval diagnosed Petitioner with polyneuropathy, etiology unknown. *Id*. He recommended that Petitioner undergo an EMG nerve conduction study (although he made no reference to the October 2009 EMG).[11] *Id*.

The EMG recommended by Dr. Raval was performed on August 5, 2010, and confirmed that Petitioner had evidence of both motor and sensory polyneuropathy that was axonal in nature. Pet'r's Ex. 12 pt. 2 at 11. Ms. Auch was seen again by Dr. Raval at the end of August 2010, at which time she reported intermittent fatigue that she felt might have been a function of the gabapentin she was taking. *Id.* at 10. Dr. Raval conducted another physical examination which, again, was largely inconclusive, and he proposed that she had some kind of polyneuropathy, the etiology of which remained unknown. *Id.* He recommended that she stop taking the gabapentin to see if that alleviated her reported fatigue. *Id.*

Petitioner's follow-up visits to doctors relating to her 2010 polyneuropathy diagnosis continued throughout the rest of 2010 and into the ensuing years. She continued to report pain all

[11] Dr. Raval's treatment notes do reference the fact that a different EMG was performed at some unspecified time in the past to evaluate pain in Ms. Auch's left ankle. Pet'r's Ex. 12 pt. 2 at 28. They do not mention the October 2009 EMG.

over her body and tingling and numbness in her hands. *See, e.g.,* Pet'r's Ex. 12 pt. 1 at 38 (June 30, 2011, treatment record prepared by Dr. Raval). She also reported symptoms of being unable to walk distances due to her peripheral neuropathy and the pain sensation that developed in her feet. *Id.* at 34. The etiology for her symptoms remained unidentified, however, and the records do not reflect any speculation as to what caused her polyneuropathy from any of the doctors. Petitioner for her part speculated to her doctors that certain events in the past might have caused her current condition, including a chemical spill she cleaned up when she worked at a hospital. Pet'r's Ex. 14 at 2. Petitioner's lab results during this time were unremarkable and showed no signs of other issues. *See, e.g.,* Pet'r's Ex. 12 pt. 1 at 24.

Ms. Auch was placed on methadone to help manage her pain levels, followed by a switch to hydrocodone. Pet'r's Ex. 10 at 6. Her medicines continued to be monitored, as she reported at the Siouxland Surgery Center that she felt dizzy from the drugs she was taking. *Id.* at 3. Petitioner was placed on disability leave beginning in March 2012 (Pet'r's Ex. 15), and continued to follow up with doctors for her symptoms from polyneuropathy through 2012. Pet'r's Ex. 12 pt. 1 at 20. There are no subsequent records identifying a proposed cause for her symptoms.

II. Fact Witness Testimony

Petitioner presented five witness affidavits: one from Brittany Arens,[12] Petitioner's daughter; one from Julie Broders, Petitioner's sister; one from Rhonda K. Surface, another of Petitioner's sisters; one from Leo Hallan, an individual for whom Petitioner provided in-home care; and one from Robert Foxhoven, an employee at Petitioner's place of employment, First National Bank of Omaha. ECF No. 37 (Pet'r's Exs. 21-24). At hearing, however, only Ms. Arens and Ms. Surface testified as fact witnesses, along with Petitioner herself. Pet'r's Ex. 25; Tr. at 4, 14, 25.

Ms. Auch largely testified about her receipt of the vaccine itself and her symptoms in the days and weeks immediately following, as well as the difference in her abilities before and after the vaccination.[13] Tr. at 26-27. She generally stressed the debilitating nature of the symptoms, and persuasively explained how disconcerting it had been to experience them and the toll they had taken on her life. *Id.* at 34-35, 45-47. She also attempted generally to distinguish the symptoms she experienced after receipt of the flu vaccine from those she had previously associated with her fibromyalgia, characterizing the latter as less severe and alarming. Tr. at 38.

[12] Brittany Arens's Affidavit is signed by Brittany Auch, her maiden name. By the time of the hearing, her name had changed to Brittany Arens, because she married in the intervening period. Tr. at 4.

[13] Petitioner's testimony was for the most part consistent with the filed medical records, although not all of the events that occurred were addressed. She also did not discuss the gaps from the end of 2009 and the summer of 2010, when her polyneuropathy was formally confirmed.

The other fact witnesses recounted the changes they had witnessed in Petitioner after her receipt of the flu vaccine. All testified that prior to the vaccination, Petitioner was active and enjoyed several activities, such as long shopping trips (Tr. at 6, 8), riding several miles on her bicycle (Tr. at 18), and gardening (Tr. at 18). Ms. Auch had also been very active in her community and with her children. Tr. at 6, 16, 34. Petitioner also testified that she was involved in the church, and she spent a lot of time gardening and canning vegetables, which she enjoyed. Tr. at 34.

Though Ms. Auch acknowledged that she had suffered from fibromyalgia prior to the vaccination, the witnesses averred that Petitioner was able to cope with its effects well. Tr. at 11, 20. But there was a "dramatic change" after the vaccination, and Petitioner was very limited in what she could do going forward given the pain. *Id.* at 17. Thus, Ms. Arens recalled a visit home while in college during which she noticed that Petitioner was unable to stand for long periods and spent much of the time using a walker to get around the house. *Id.* at 8. Ms. Surface noted that Petitioner was unable to ride her bicycle anymore, could not walk more than a block or two without struggling, and had issues controlling her weight due to her inability to exercise. *Id* at 17-18. Petitioner herself admitted that she had to use a motorized cart while shopping because she could not walk around an entire store without pain. *Id.* at 46. Additionally, she previously acted as a caregiver to a paraplegic from 2006-2009, which she was eventually unable to continue doing because of her weakness and numbness. Pet'r's Ex. 23 at 2. Overall, Petitioner testified that her constant pain and numbness had taken away her ability to participate in activities she once enjoyed and worsened over time. Tr. at 47.

III. Expert Testimony

A. *Dr. Robert Neumayr*

Petitioner's initial expert report filed in the action came in the form of a one-page letter from Dr. Neumayr, one of her treaters[14] at Yankton Medical Clinic from October 2009 (although the record does not suggest that his care of Petitioner, or direction of treatment, predominated over other caregivers from this same period, such as Drs. Fanta or Zimprich). *See* Letter, dated May 21, 2014, filed as Pet'r's Ex. 28 (ECF No. 52-2) on June 4, 2014 ("First Neumayr Rep."). Dr. Neumayr's initial opinion letter was perfunctory and conclusory; beyond setting forth an opinion as to the causal role of the flu vaccine in Ms. Auch's polyneuropathy, the letter provided no explanation or scientific support for its statements.

[14] Dr. Neumayr is a practicing doctor in the Internal Medicine Department at Yankton Medical Clinic, P.C., in Yankton, South Dakota, where he treats Ms. Auch as a patient. Dr. Neumayr received his B.S. in Pharmacy and M.S. in Pharmacology from South Dakota State University, followed by a PhD in Pharmacology from the University of Utah in 1974. Pet'r's Ex. 29 at 1. He received his M.D. from the University of Utah in 1975, and completed a residency in internal medicine at the University of Utah Affiliated Hospitals from 1975-1978. *Id*. He is board certified in internal medicine, a member of the American Medical Association, and holds an active license to practice medicine in South Dakota. *Id*. Dr. Neumayr has also conducted research in various areas of neuropharmacology, specifically in the study of the central control of the autonomic nervous system. *Id.* at 2.

At a subsequent status conference held in June 2014, I noted to Petitioner that Dr. Neumayr's report was substantively thin, and Petitioner agreed, stating that Dr. Neumayr intended to file a follow-up report. *See* June 18, 2014 Scheduling Order (ECF No. 53). I therefore ordered her to do so – and after receiving two extensions of time in which to act, Petitioner filed a second report from Dr. Neumayr on October 20, 2014. *See* Report, dated October 16, 2014, filed as Pet'r's Ex. 30 (ECF No. 57-1) ("Second Neumayr Rep.").

The second report from Dr. Neumayr is still in letter form, but is now three pages in length rather than one. In it, Dr. Neumayr recounts Ms. Auch's October 2009 symptoms and related treatment. Second Neumayr Rep. at 1. He sets forth the opinion that a polyneuropathy is an autoimmune condition, and that it is "well established" that the flu vaccine can cause such a condition – although his second report included no medical citations or references in support of this contention. *Id.* at 2. He went on to propose that Ms. Auch's immune system appeared to be "hypersensitive" to the flu vaccine, as evidenced by her initial immediate reaction, noting that he had (when treating Ms. Auch in October 2009) proposed that she had experienced an allergic reaction to the vaccine. *Id.* at 3. He also stated that the seven-day period that elapsed from the time of her vaccination to her second round of symptoms was medically appropriate for an autoimmune reaction – again without offering medical or scientific support for the point. *Id.*

Dr. Neumayr was not called as a witness at the August 2016 hearing.

B. *Dr. Lawrence Steinman*

Petitioner offered Dr. Steinman's expert report in reaction to Dr. Lancaster's report (discussed in more detail below) filed by Respondent. The core of Dr. Steinman's opinion is reflected in his written report, although he provided some additional detail in his testimony at hearing as well. *See* Report, dated July 5, 2015, filed as Pet'r's Ex. 31 (ECF No. 65-1) ("Steinman Rep.").

Dr. Steinman is a professor in Stanford University's Departments of Neurology, Pediatrics, and Genetics, and the chair of Stanford's Immunology Program. Steinman Rep. at 2-3; *see also* Pet'r's Ex. 32 (Dr. Steinman's curriculum vitae). He has been elected to the Institute of Medicine ("IOM") in neurology, and he has published more than 400 articles, including articles related to his research on autoimmune disease and molecular mimicry. Pet'r's Ex. 32 at 2. He is also board certified by the American Board of Psychiatry and Neurology. *Id*. Dr. Steinman's research appears to focus more on the central nervous system and related neuropathies, as opposed to peripheral neuropathies.

Dr. Steinman's report proposes a theory that he has advanced in many other Vaccine Program cases: that the flu vaccine can prompt an autoimmune response, causing individuals to experience a demyelinating injury to the central or peripheral nervous system (here, an inflammatory polyneuropathy affecting the limbs).[15] Given his overall experience studying not just central nervous system illnesses, like multiple sclerosis, but the autoimmune character of those conditions, he was qualified to testify on the issues in dispute in this case.

Thus, Dr. Steinman opined that the version of flu vaccine that Ms. Auch received (Fluzone) contained wild flu virus strains that have protein components that are capable of cross-reacting with the structures of myelin basic protein – a primary component of human nerves. Steinman Rep. at 3-5, 13-16. As a result, an autoimmune process begins, encouraging the production of antibodies that erroneously attack self-cells and structures. Tr. at 89-90. For a polyneuropathy such as that Ms. Auch alleges to have experienced, Dr. Steinman proposed that the nerve axon, rather than its sheath, was the primary target (via nerve gangliosides on the axon surface), making the disease in this case a bit different from a more acute form of neuropathy, such as GBS, which is characterized by an autoimmune attack on the nerve myelin sheath and is associated with greater amounts of inflammation and demyelination. Steinman Rep. at 10-13, 17; Tr. at 93-94.

Dr. Steinman offered the mechanism of molecular mimicry to explain how the flu vaccine could prompt an autoimmune reaction. Steinman Rep. at 9-17; Tr. at 90. In essence, molecular mimicry is defined as a "sequence and/or conformational homology between an exogenous agent (foreign antigen) and self-antigen leading to the development of tissue damage and clinical disease from antibodies and T cells directed initially against the exogenous agent that also react against self-antigen." Institute of Medicine, *Adverse Effects of Vaccines: Evidence and Causality* at 70 (K. Stratton et al., eds. 2012) [hereinafter "Adverse Effects of Vaccines"]; *see also* L. Steinman, *Autoimmune Disease*, 269 Scientific American 106-14 (Sept. 1993) (Pet'r's Ex. 55). Dr. Steinman's expert report provided a highly detailed walkthrough of possible mimics between protein sequences contained in components of the flu vaccine and of the myelin basic protein, offering substantial research involving other demyelinating illnesses or the wild flu virus to corroborate his opinion.[16]

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[15] *See, e.g., Dillon v. Sec'y of Health & Human Servs.*, No. 10-850V, 2013 WL 3745900, at *9 (Fed. Cl. Spec. Mstr. June 25, 2013) (denying entitlement to a petitioner who alleged the influenza vaccine caused her demyelinating transverse myelitis), *mot. for review den'd*, 114 Fed. Cl. 236 (2014); *Brown v. Sec'y of Health & Human Servs.*, No. 09-426V, 2011 WL 5029865, at *21 (Fed. Cl. Spec. Mstr. Sept. 30, 2011) (finding the influenza vaccine more likely than not caused a petitioner's demyelinating injury of acute disseminated encephalomyelitis).

[16] Thus, Dr. Steinman's report attempts to identify the specific protein peptide sequence found in components of the flu vaccine that would be homologous (meaning corresponding in structure, position, origin, etc. (*see Dorland's* at 868)) to like sequences found in the myelin basic protein. *See, e.g.,* Steinman Rep. at 14-15. I note, however, that Vaccine Program petitioners are not required to establish a specific biological mechanism. *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548-49 (Fed. Cir. 1994). More importantly, my decision does not turn on Petitioner's success in establishing a plausible causation theory (and in any event, the causation theory espoused herein has found

Dr. Steinman next engaged in an overview of Ms. Auch's medical history, linking it to his theory. Steinman Rep. at 5-8. He largely accepted the factual summary and conclusions about her history as set forth in Dr. Neumayr's letter, however, without any separate analysis of his own. Significantly, he differentiated Ms. Auch's reported initial reaction to the flu vaccine as probably the product of an allergic reaction to it (akin to Dr. Neumayr's "hypersensitivity" hypothesis) from the symptoms she reported the following week (and that Petitioner alleges were the true start of her polyneuropathy). Steinman Rep. at 7-8; Tr. at 96-98, 145-46.

As support for the claimed injury, Dr. Steinman made special reference to the "nerve conduction study done 10 months after the FluZone vaccination," or on August 5, 2010 – despite the fact that the first such study (performed in the same month as the vaccination at issue) had not at the time been considered convincing evidence of any neuropathy at all. Pet'r's Ex. 2 pt. 1 at 2; Pet'r's Ex. 60 at 1; Steinman Rep. at 6. His report later attempted to rebut the negative findings from the first EMG test results, as pointed out by Dr. Lancaster, by arguing that the steroid treatment that Ms. Auch received just before (Solu-Medrol) might explain the negative result. Steinman Rep. at 19. At trial, he expanded on this point:

> It's a very potent drug that does a lot of things to the immune system, the endocrine system. Water metabolism, swelling – swelling in nerves. There's just – the good news about the drug, it's often very powerful and does a lot of things. The bad news about the drug, it has what we call pleiotropic effects, many different effects on physiology. So, that could have been a confound, the fact that she got the Depo-Medrol.[17] Not a confound in the treatment, but a confound in why this test was deemed unremarkable.
> It's something that's seen with drugs that are used for, let's say, the chronic version of inflammatory demyelinating polyneuropathy, . . . you see improvement so rapidly that it can't be simply explained as – on the basis of immunologic phenomenon.

Tr. at 135-36.

Dr. Steinman also took issue with Dr. Lancaster's proposal that the possible cause of Ms. Auch's polyneuropathy was diabetes, noting that (a) no treater had ever so proposed, (b) the record did not include any corroborative proof supporting this possibility, and (c) if in fact Ms. Auch was diabetic, he reasonably would have expected her treaters to have caught the condition (and so the fact that they never proposed it was significant). Tr. at 125-28. He also disagreed that her symptoms reflected a diabetic neuropathy, reasoning in part that onset would be more gradual,

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success repeatedly in other Program cases as reliable and persuasive), so this decision will not contain a detailed recitation of the science and other proof offered in its support.

[17] Both in his expert report and trial testimony, Dr. Steinman referred to the steroid Ms. Auch received as "Depo-Medrol," but the record reveals that she actually received Solu-Medrol. However, these are both trademarked names of similar versions of methylprednisolone.

rather than the acute symptoms Ms. Auch first displayed in the weeks immediately after she received the flu vaccine. *Id.* at 129-30.

C. *Dr. Eric Lancaster*

Dr. Lancaster testified on behalf of Respondent at hearing and also offered two reports in this matter. The first was filed on January 30, 2015, and responded to both of Dr. Neumayr's letter-reports. *See* Report, dated January 25, 2015, filed as Resp't's Ex. A (ECF No. 59-1) ("First Lancaster Rep."). The second, filed on September 14, 2015, responded to Dr. Steinman's sole report. *See* Report, dated September 10, 2015, filed as Resp't's Ex. G (ECF No. 69-1) ("Second Lancaster Rep."). Dr. Lancaster's testimony at hearing was in most respects consistent with his reports, although (as noted below) it leaned more in the direction of his second report on certain topics.[18]

Dr. Lancaster is a clinical doctor at the Center for Autoimmune Neurology at the University of Pennsylvania, as well as an assistant professor of neurology at the University of Pennsylvania. Resp't's Ex. B at 1. He received his M.D. from the University of Maryland in 2003, followed by a neurology residency at the University of Pennsylvania from 2004-2007. *Id.* Dr. Lancaster's research focuses on antibody-mediated neurological disorders, and he sees patients with complex autoantibody disorders on a regular basis. Resp't's Ex. B at 1.

Dr. Lancaster challenged Petitioner's contention that she had experienced a polyneuropathy due to the October 2009 vaccination. And although he did not dispute that she had been properly diagnosed with a form of peripheral polyneuropathy in 2010 (which his second report specifically characterized as a "mild, chronic, distal symmetrical polyneuropathy"), he disagreed that it was in any way linked to her receipt of the flu vaccine in the year before. Tr. at 173-76, 178-79; Second Lancaster Rep. at 2. His testimony also differed from Dr. Steinman's in how he evaluated Ms. Auch's immediate symptoms versus those she experienced in the weeks after she received the flu vaccine – and how he compared the 2009 symptoms with those from 2010.

Dr. Steinman testified that Petitioner's symptoms beginning a week after her October 6, 2009, vaccination revealed the onset of her neuropathy, but Dr. Lancaster felt these symptoms were equally consistent with Ms. Auch's preexisting conditions such as fibromyalgia. Tr. at 173. Based on his review of the medical records, Dr. Lancaster felt that immediate treaters appropriately included peripheral neuropathy in the differential diagnosis, but the extremely acute and

[18] Thus, Dr. Lancaster's first expert report reacted to Dr. Neumayr's two fairly bare-bones letter-reports, while the second addressed Dr. Steinman's lengthier and more substantive opinion. In addition, at trial Dr. Lancaster was more emphatic in agreeing with Petitioner's 2010 diagnosis of a polyneuropathy; at the time of his first report, by contrast, he was skeptical of the diagnosis. *See* First Lancaster Rep. at 15.

reportedly-debilitating nature of the symptoms ("very rapid development of the weakness over a period of seconds") made a demyelinating injury unlikely (which would take longer to manifest in his experience). *Id.* at 174-75. He also noted that these reported symptoms were not corroborated by any other signs of a peripheral neuropathy, such as reflex function or sensory function, or test results. *Id.* at 175, 203-04. And he questioned whether an individual suffering from a severe neuropathic injury characterized by sudden limb malfunction could have the symptoms improve so quickly as well. *Id.* at 175 ("[a] patient with Guillain-Barré will worsen over hours, but they can't suddenly get all better and then suddenly get all sick and then suddenly get all better again over just the course of hours to days."); Second Lancaster Rep. at 4.

In addition to the above, Dr. Lancaster found persuasive the results of the neurologic work-up Ms. Auch received in October 2009 from treaters like Dr. Zimprich. Tr. at 177; Second Lancaster Rep. at 2. Her treaters had specifically sought input from specialists to evaluate if a neuropathy such as GBS were present, and then after a series of tests (including the October 2009 EMG), determined it was not. Pet'r's Ex. 2 pt. 1 at 9. And treatments that would have been considered if in fact Ms. Auch's neuropathy was acute enough to affect her limb function, such as plasmapheresis or IVIG, were neither proposed nor provided. Tr. at 192.

Dr. Lancaster also, however, considered Ms. Auch's reported immediate symptoms to be more significant than Dr. Steinman, deeming them as likely related to the symptoms she reported later that month. Thus, while Dr. Steinman proposed that the blurry vision and sudden symptoms that Petitioner reported were evidence of an underlying allergic reaction to the flu vaccine, Dr. Lancaster felt the first-day symptoms were related to the more reportedly-severe symptoms occurring later that month – all of which he opined were probably attributable to her preexisting conditions, such as her depression or fibromyalgia. Tr. at 176; First Lancaster Rep. at 15, 22. He did not accept Dr. Neumayr's assertion that the flu vaccine might have aggravated some underlying intolerance, and/or that Ms. Auch even possessed such an intolerance at all based on her claimed immediate symptoms. Tr. at 189-91; First Lancaster Rep. at 18, 22.

Dr. Lancaster largely accepted the 2010 polyneuropathy diagnosis, observing that the EMG results corroborated it, along with Dr. Raval's interpretation of the EMG. Tr. at 184, 199; Pet'r's Ex. 12 pt. 2 at 11. But he denied that Petitioner's illness could possibly be linked to a vaccination Petitioner had received 10 months before. Tr. at 194-95.[19] Simply too much time had passed – with

[19] Dr. Lancaster's reports and hearing testimony also discuss his views as to the likelihood that the flu vaccine could cause a neuropathy at all, and/or do so via the proposed mechanism of molecular mimicry, questioning whether the science and related hypotheses included in Dr. Steinman's expert report and testimony applied herein. Tr. at 192-94; Second Lancaster Rep. at 5-6. As I informed the parties at the start of Dr. Steinman's testimony, however, I did not deem these *Althen* prong one issues to be central to disposition of this case, and urged both experts to tailor their testimony accordingly. *See, e.g.,* Tr. at 84-85. In fact, there are numerous Vaccine Program decisions in which the flu vaccine has been persuasively demonstrated to be causally associated with a variety of central and peripheral neuropathies. *See, e.g., Barone v. Sec'y of Health & Human Servs.*, No. 11-707V, 2014 WL 6834557 (Fed. Cl. Spec. Mstr. Nov. 12, 2014); *Stewart v. Sec'y of Health & Human Servs.*, No. 06-777V, 2011 WL 3241585 (Fed. Cl. Spec.

a demonstrated cessation of symptoms for most of 2010 – for him to accept that her subsequent diagnosis was connected to a vaccination received almost a year before.

In rejecting the record evidence about Ms. Auch's claimed October 2009 post-vaccination symptoms, while embracing evidence of similar symptoms from 2010 as supportive of a polyneuropathy diagnosis, Dr. Lancaster placed great stock in the result of the EMG tests performed at those two points in time. Thus, he noted that if in fact Ms. Auch's reported symptoms in the first half of October had been as severe as she claimed (an inability to walk or move coupled with profound weakness) such that they reflected an acute demyelinating incident or similar nerve damage, then the EMG test performed in October 2009 should have corroborated that damage – when in fact the results did not show any convincing evidence of a neuropathy. Tr. at 203-205; Pet'r's Ex. 2 pt. 1 at 2; Pet'r's Ex. 60 at 1.[20]

Dr. Lancaster was particularly critical of Dr. Steinman's assertion that Ms. Auch's normal EMG results from October 2009 could be explained by the fact that she had recently been treated with a steroid that may have thrown off the test results. Tr. at 181-83. At trial, he explained in detail the process of performing an EMG, noting that he had just performed several within a week of his testimony. *Id.* at 210. Dr. Lancaster has considerable experience with EMGs, having performed (and reviewed the results of) around 2,000 in his entire career, while performing 12 to 18 in any given month. *Id.* at 171. He explained in detail the process of testing – and particularly the sensitivity of that testing in measuring severity and age of injury to different parts of the nerve. *Id.* at 211-13.

In his supplemental report, Dr. Lancaster observed that damage to nerves sufficient to be diagnosed as a severe polyneuropathy of the kind alleged herein could not be reversed so quickly merely through receiving a steroidal treatment, such that a subsequent EMG would show nothing abnormal. Lancaster Supp. Rep. at 6 ("[b]asically, it is completely impossible for a neuropathy to cause severe numbness or weakness and recover over a few days to such a degree that the EMG/NCS is normal. Even if steroids completely stopped an inflammatory process, the deficits would remain visible on a [nerve conduction study] for weeks thereafter as the nerves repaired themselves"); Tr. at 215. He also noted that if Dr. Steinman's assertions were correct, then steroids would in effect function as a cure for severe neuropathies like GBS, when in fact treaters understood that they did not serve that function (even if they could be ameliorative over time). Tr. at 216 ("if [steroid treatments] could suddenly normalize your nerve conduction studies, that would

Mstr. July 8, 2011); *Daily v. Sec'y of Health & Human Servs.*, No. 07-173V, 2011 WL 2174535 (Fed. Cl. Spec. Mstr. May 11, 2011). I therefore do not address herein the portions of the reports or testimony that related to such matters, which for present purposes are tertiary to the real issues in dispute.

[20] Although Dr. Lancaster did not have the benefit of reviewing the October 2009 EMG results at the time he prepared his reports or testified, they are in fact consistent with his supposition, which was based on the references to the tests contained in the contemporaneous records. Pet'r's Ex. 60 at 1.

go hand-in-hand with the drug being a miracle cure, . . . and everybody with [GBS], we would load them up with [the treatment], they'd pop right out of bed and they'd be fantastic.").[21]

Finally, Dr. Lancaster proposed an alternative explanation for Ms. Auch's 2009 symptoms – diabetes – as more consistent with the record. Tr. at 179-80, 195-96; First Lancaster Rep. at 16-17. He was not able to point to any such diagnosis in the record, however, admitting that based upon what records he had reviewed of glucose level testing from blood work, "it is not clear whether [Petitioner] is diabetic or prediabetic." First Lancaster Rep. at 16. Dr. Steinman for his part disputed that Ms. Auch suffered from some form of diabetic neuropathy, noting that he would have expected some of her treaters to have considered the possibility. The fact that they never proposed it as a diagnosis in any of the treatment records, despite many opportunities to do so (and to perform the sorts of tests that would easily confirm existence of the condition) was evidence to him that it was not deemed an applicable diagnosis to Ms. Auch. Tr. at 129-30. Dr. Steinman also questioned whether her form of neuropathy had the characteristics of a diabetic form (Tr. at 128-29).

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[21] At the very end of the August 2016 hearing, Petitioner recalled Dr. Steinman to the stand for a rebuttal point relevant to this particular issue. *See* Tr. at 222-25. Dr. Steinman referenced Respondent's Exhibit E (M. Dalakas, *Pathogenesis of Immune-Mediated Neuropathies*, 1852 Biochimica et Biophysica Acta 4:658-66 (May 2014) ("Dalakas")) and read directly from a portion of it. His intent was to show that polyneuropathic symptoms could in fact fluctuate rapidly – and this would explain both why (a) Ms. Auch's symptoms appeared to swing so dramatically in October 2009 and (b) the steroidal treatment that Dr. Lancaster discounted as masking EMG results might in fact have performed as Dr. Steinman proposed. *Id.* at 223-24.

The section of the Dalakas article from which Dr. Steinman read, however, does not really support the main proposition for which it was cited (*i.e.,* that steroidal treatment could cause a sufficiently sudden improvement in Ms. Auch's condition to confuse the EMG test results). Entitled "emerging target antigens in the nodal regions: an explanation for conduction block and rapid recovery," the section's focus is the search for the antigen targets that cause CIDP or other peripheral neuropathies. Dalakas's authors proposed that one place to look for them was in the "nodal or paranodal regions" of nerves rather than in the compact myelin. This was based on the fact that two known effective treatments for peripheral neuropathies – plasmapheresis or IVIG – could produce rapid recovery as reflected in a patient's reported pain level or feeling of health, despite the fact that the remyelination process would itself take much longer. Dalakas at 5. This fact led the Dalakas authors to propose that the treatments were likely inducing a "'minute-to-minute' blockade" at the nodal points that had a salutary effect independent of the remyelination process – and therefore these nodes might be the location of the antibodies that were at the core of the autoimmune process, making them a favorable place in which to search. *Id.*

But the treatments specified in this article are distinguishable from the steroid treatments Ms. Auch received (and which, as noted above, were administered prior to her first EMG tests). More significantly, the fact that steroidal treatments might have ameliorated Ms. Auch's pain, and thus been rapidly effective in making her feel better, does not mean that they would have thrown off tests that exist to measure underlying nerve function or deterioration. Tr. at 215-16. Dalakas itself notes a difference between the speed at which the treatments it discusses would "work" and the slower, ongoing remyelination process – a process the EMG is designed explicitly to test, rather than whether a patient feels better.

Petitioner otherwise offered no literature in support of this rebuttal contention, such as an article discussing what kinds of factors could skew or impact EMG test results.

IV. Procedural History

Ms. Auch filed her Petition on October 4, 2012. ECF No. 1. In it, she alleged that she suffered significant fatigue, headache, flushing, tingling, nausea, loss of muscle control, lower extremity weakness, and shortness of breath as a result of her receipt of the influenza vaccination on October 6, 2009. Pet. at 1-2. After several motions for extensions of time, Petitioner filed medical records in April of 2013, followed by a statement of completion on May 13, 2013. ECF No. 23. Petitioner thereafter filed additional medical records. ECF No. 28.

Respondent filed her Rule 4(c) Report on September 30, 2013, asserting that Ms. Auch was not entitled to compensation because she could not carry her burden of proof under *Althen*. Respondent's Rule 4(c) Report (ECF No. 31). Specifically, Respondent alleged that Petitioner's existing significant health issues could account for most, if not all, of the symptoms she attributes to the flu vaccine. ECF No. 31 at 14. Additionally, Respondent notes that Petitioner told at least three different providers that the majority of her symptoms preceded vaccination. *Id.*

The case was re-assigned to me on April 7, 2014. ECF No. 46. After additional extensions of time, Petitioner finally filed the first opinion letter from Dr. Neumayr on June 4, 2014. ECF No. 52-2 (Pet'r's Ex. 28). In a subsequent status conference, Petitioner acknowledged that the expert opinion was only "partially-complete," and after again requesting several extensions of time, Petitioner filed a somewhat longer report from Dr. Neumayr. ECF No. 57 (Pet'r's Ex. 30).

On January 30, 2015, Respondent filed Dr. Lancaster's first report. ECF No. 59 (Resp't's Ex. A). Petitioner was given the opportunity to file a supplemental expert report in response, and after an extremely protracted amount of time and admonishments for failing to comply with my orders, Petitioner filed Dr. Steinman's report on July 8, 2015. ECF No. 65 (Pet'r's Ex. 31). Respondent then filed a supplemental report of Dr. Lancaster in response on September 14, 2015. ECF No. 69 (Resp't's Ex. G).

Thereafter, an entitlement hearing was scheduled for August 24-25, 2016 in Omaha, Nebraska. ECF No. 70. Petitioner filed her prehearing submissions on June 6, 2016 (ECF No. 76), and Respondent filed her prehearing submissions on July 1, 2016. ECF No. 78. The parties elected not to file post-hearing briefs. Tr. at 228-29. After the hearing, Petitioner was directed to file the medical literature cited by Dr. Steinman in his expert report, which she filed on November 23, 2016. ECF Nos. 86-88 (Pet'r's Exs. 36-58).

Though it originally had been determined that a copy of Petitioner's first EMG performed on October 15, 2009, could not be produced (ECF No. 84), Petitioner was ultimately able to file those EMG results, as well as Dr. Zimprich's interpretation of them, on December 29, 2016. ECF No. 89 (Pet'r's Exs. 59-60). I have incorporated discussion of these recently-filed record materials into my decision.

V. Applicable Legal Standards

A. Petitioner's Overall Burden in Vaccine Program Cases

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that she suffered a "Table Injury" – *i.e.*, an injury falling within the Vaccine Injury Table – corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that her illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Human Servs*., 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Human Servs*., 440 F.3d 1317, 1320 (Fed. Cir. 2006).[22] In this case, Petitioner does not assert a Table claim.

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs*., 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Human Servs*., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on her assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen*: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278.

[22] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Human Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Human Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd*, 104 F. App'x 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Human Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen*, 35 F.3d at 548. Such a theory must only be "legally probable, not medically or scientifically certain." *Id*. at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325-26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec'y of Health & Human Servs.*, 121 Fed. Cl. 230, 245 (2015) ("[p]lausibility . . . in many cases *may* be enough to satisfy *Althen* prong one" (emphasis in original)), *rev'd on other grounds*, No. 2015-5097 (Fed. Cir. Jan. 3, 2017). But this does not negate or reduce a petitioner's ultimate burden to establish her overall entitlement to damages by preponderant evidence. *W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted).[23]

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

[23] There is ample contrary authority for the more straightforward proposition that the first *Althen* prong, like the overall test itself, simply applies a preponderance standard when evaluating if a reliable and plausible causal theory has been established. *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1350 (Fed. Cir. 2010). For purposes of the present analysis, I am stressing those cases focusing on the *plausibility* of the causal theory proposed, as opposed to whether preponderant evidence supports it, in order to avoid imposing on Petitioner a greater evidentiary burden than the law requires. This does not, however, change the fact that *any* theory's plausibility, for purposes of satisfying the *Althen* test, is properly analyzed by subjecting its components to the *Daubert* tests for scientific reliability. *Terran v. Sec'y of Health & Human Servs*., 195 F.3d 1302, 1316 (Fed. Cir. 1999). In any event, my decision herein does not turn on Petitioner's success in establishing a medical causation theory.

However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct – that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record – including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Caves v. Sec'y of Dep't of Health & Human Servs.*, 100 Fed. Cl. 119, 136 (2011), *aff'd*, 463 F. App'x 932 (Fed. Cir. 2012); *Veryzer v. Sec'y of Health & Human Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 Fed. App'x 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id*. at 1352; *Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 2013 WL 1896173 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Human Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. Law Governing Analysis of Fact Testimony and Evidence

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as "the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then

required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such a determination is evidenced by a rational determination).

Medical records that are created contemporaneously with the events they describe are presumed to be accurate and "complete" (*i.e*., presenting all relevant information on a patient's health problems). *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Human Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Human Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). This presumption is based on the linked propositions that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Human Servs*., No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Human Servs*., 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms. It is equally unlikely that pediatric neurologists, who are trained in taking medical histories concerning the onset of neurologically significant symptoms, would consistently but erroneously report the onset of seizures a week after they in fact occurred").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneously medical records are generally found to be deserving of greater evidentiary weight than oral testimony – especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd*, 968 F.2d 1226 (Fed. Cir.), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Human Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon

common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Human Servs*., No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y Health & Human Servs*., 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. Analysis of Expert Testimony

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc*., 509 U.S. 579, 594-96 (1993). *See Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999)). "The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592-95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial fora (such as the district courts). *Daubert* factors are usually

employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable and/or could confuse a jury. In Vaccine Program cases, by contrast, these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Human Servs.*, 94 Fed. Cl. 53, 66-67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742-45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts of her own in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d at 1347 (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Human Servs.*, No. 08-601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 Fed. App'x 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325-26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Human Servs*., 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

In determining whether a particular expert's testimony was reliable or credible, I may consider whether the expert offers an opinion that exceeds his training or competence, whether across the board or with respect to any particular element of testimony. *Walton v. Sec'y of Health & Human Servs.*, No. 04-503V, 2007 WL 1467307, at *17-18 (Fed. Cl. Spec. Mstr. Apr. 30, 2007) (otolaryngologist not well suited to testify about disciplines other than her own specialty). While (in keeping with the liberality with which evidence offered in Vaccine Program cases is treated) I heard and have considered all of the testimony of the experts offered at the entitlement hearing, I may properly evaluate, and give appropriate weight to, whether certain testimony is beyond a particular expert's purview. *See, e.g.*, *King v. Sec'y of Health & Human Servs.*, No. 03-584V, 2010 WL 892296, at *78-79 (Fed. Cl. Spec. Mstr. Mar. 12, 2010) (petitioner's expert far less qualified

to offer opinion on general causation issues pertaining to autism than specific issues pertaining to the petitioner's actual medical history, given the nature of the expert's qualifications).

D. Consideration of Medical Literature

Both parties filed medical and scientific literature in this case, including some articles (such as those discussing molecular mimicry and protein sequences in vaccines) that do not factor into the outcome of this decision. I have reviewed all of the medical literature submitted in this case, but I discuss only those articles that are most relevant to my determination and/or are central to Petitioner's case – just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Human Servs.*, No. 2015-5072, 2016 WL 1358616, at *5 (Fed. Cir. Apr. 6, 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. v. Sec'y of Health & Human Servs.,* 527 F. App'x 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to — and likely undermines — the conclusion that it was not considered").

ANALYSIS

This case does not turn on Petitioner's success in establishing the first *Althen* prong – although she has satisfied this element of her overall burden of proof. Many other petitioners have demonstrated that the flu vaccine can cause a variety of neuropathies. *See, e.g., Stewart v. Sec'y of Health & Human Servs.,* No. 06-777V, 2011 WL 3241585 (Fed. Cl. Spec. Mstr. July 8, 2011) (petitioner was entitled to compensation in a flu/GBS case); *Daily v. Sec'y of Health & Human Servs.,* No. 07-173V, 2011 WL 2174535 (Fed. Cl. Spec. Mstr. May 11, 2011) (entitlement proven on a claim that the flu vaccine more likely than not caused the petitioner to develop chronic inflammatory demyelinating polyneuropathy); *Doe/06 v. Sec'y of Health & Human Servs.*, 2007 WL 3120297 (Fed. Cl. Spec. Mstr. Oct. 18, 2007) (granting entitlement in a flu/small fiber neuropathy case). Based on the expert testimony and reports, as well as the submitted literature, preponderant evidence supports Petitioner's theory that the flu vaccine could plausibly cause some kind of neuropathy, whether severe or mild, and also that the proposed mechanism, molecular mimicry, is a reliable explanation for how the flu vaccine would induce an autoimmune reaction that would damage an individual's myelin or nerves.

There are other factual matters that are largely undisputed, or readily resolved in Petitioner's favor. For example, the parties agree that Ms. Auch was correctly diagnosed with some form of polyneuropathy in 2010. Also, I do not find persuasive Respondent's arguments that diabetes was a plausible alternative cause for her condition, given that none of her treaters ever considered the possibility that she even suffered from diabetes, as Dr. Steinman suggested

would be expected for a person of Petitioner's age, and Respondent has not pointed to record evidence that would support her contention.

The above does not, however, end the analysis. The question before me, based on the record as interpreted by both side's experts, is whether *in this particular case* the flu vaccine Ms. Auch received in October 2009 caused severe neuropathic symptoms in the ensuing two months, followed by a lengthy lull, ultimately resulting in a formal diagnosis of polyneuropathy nearly a year later attributable to the vaccine. This raises a question as to *Althen* prongs two and three. I find that it is more likely than not that the flu vaccine did not cause Ms. Auch's 2010-diagnosed polyneuropathy.

A. Ms. Auch's Immediate Symptoms Do not Bear on Her Claim.

The parties dispute somewhat the nature of Ms. Auch's immediate reaction to the flu vaccine received on October 6, 2009. As noted above, Petitioner alleges that on the same day she received the vaccine, she experienced blurry vision and felt a strange and disorienting sensation that alarmed her enough to cause her to visit the ER. Petitioner distinguishes that reaction from the symptoms that began either on October 9th or 13th, viewing her initial reaction as an allergic response to the vaccine not linked to her ultimate polyneuropathy, which she argues began a week later. Respondent, by contrast, believes ***all*** of the October 2009 symptoms are of a piece, and reflect ongoing fibromyalgia (or perhaps a psychosomatic reaction at the same time). Overall, the evidence is somewhat confused as to the etiology of Petitioner's immediate symptoms, making it difficult to say not only what they really were, but whether they were vaccine-caused, as Petitioner alleges.[24] But I need not resolve those questions, given that Petitioner's own theory argues for onset of her claimed injury beginning around a week after vaccination.

B. Petitioner Has Not Demonstrated that Her October 2009 Symptoms Were Neuropathic or Vaccine-Related.

The medical record does not permit the conclusion that Ms. Auch was experiencing a vaccine-induced neuropathy in October 2009. Beginning with her second ER visit on October 13, 2009, and subsequent hospitalization, Petitioner had the benefit of a fairly comprehensive evaluation in which a number of possible explanations for her symptoms were explored – including the flu vaccine. But immediate treaters ultimately rejected the concept that she was

[24] Thus, Petitioner alleged, without much evidentiary support beyond Dr. Steinman's proposal and Ms. Auch's own testimony, that Ms. Auch had previously experienced similar reactions to the flu vaccine that could be deemed allergic. At the same time, however, Respondent proposed the inference (based on some record evidence but not firmly established) that Ms. Auch may simply have been reacting fearfully to the vaccine, given her past history of anxiety and the fact that the symptoms she initially reported were not corroborated by treaters.

suffering from any kind of acute neuropathy. Not only did no test results corroborate the existence of a neuropathy, but Ms. Auch's sudden recoveries from her symptoms (whereby she was able to ambulate not long after ER trips inspired by her immediately-prior reported inability to do so) rebut the conclusion that she was, at that time, experiencing a severe neuropathic vaccine reaction. At most, treaters proposed that Petitioner might be suffering from POTS – yet even that tentative diagnosis was later abandoned. Pet'r's Ex. 2 pt. 1 at 1; Pet'r's Ex. 8 at 4, 6.

Thus, although neuropathy was included in the immediate treaters' differential diagnoses, it was never confirmed by any test results or other evidence. Dr. Lancaster also persuasively established that a true, acute vaccine reaction rising to the level of a neuropathy (like GBS) would more likely than not have been far more debilitating than what Petitioner actually experienced. Whatever Ms. Auch's illness was, it was not deemed a neuropathy – and ultimately no explanation was offered for its cause. Petitioner has therefore offered insufficient preponderant evidence to support her proposed explanation for her symptoms.

The October 2009 EMG is an important piece of evidence undermining Petitioner's assertion that she was suffering from a neuropathy. Had Ms. Auch been experiencing the kind of nerve damage from demyelination sufficient to produce total limb malfunction or the degree of weakness and parasthesias she alleged, an EMG would reasonably be expected to detect it. Tr. at 203-05. Indeed, Respondent's expert Dr. Lancaster credited the August 2010 EMG as confirming Ms. Auch's subsequent polyneuropathy. By contrast, the October 2009 EMG suggested to contemporaneous treaters that Ms. Auch did not have a demyelinating condition, and therefore they never so diagnosed her. The now-produced results from that test are consistent with the treatment record's references to it. Pet'r's Exs. 59-60.

Dr. Steinman dismissed the value of the 2009 EMG results, noting that by the time it was performed Ms. Auch had already received steroid treatments, which in his opinion would likely mute the results of such a test. But Petitioner did not bulwark that assertion with reliable evidence, such as literature or medical studies confirming the effect proposed by Dr. Steinman.[25] The medical history also casts some doubt on his assertion. Notably, Petitioner received the Solu-Medrol the night she was first admitted to the Yankton hospital on October 13, 2009, after going to the ER for a second time – but the record is devoid of any mention of the drug being administered again. It thus cannot be assumed that the drug's potency would persist at the same level when the EMG was performed two days later, on October 15th.

Moreover, even if the EMG had been performed close enough in time for the drug to potentially affect the test results, Dr. Steinman did not persuasively establish that a corticosteroid *would* inherently do so. On this topic, the specific experience and qualifications of the parties' two

[25] As noted above, the sole piece of literature Dr. Steinman referenced in rebuttal (Tr. at 223-25) did not persuasively support his argument.

testifying experts impacted the weight I give to their counter-assertions. While Dr. Steinman was a very qualified expert overall for the matters in dispute, and was highly persuasive on matters that go directly to his prime areas of expertise (such as autoimmune diseases generally or the mechanisms by which they may occur), I deem him somewhat less qualified on the topic of EMGs than Dr. Lancaster, who more regularly performs and interprets them in his day-to-day medical practice. Tr. at 171, 210-13. Dr. Lancaster persuasively explained that receipt of steroids prior to the administration of an EMG would not, in his experience, result in a "clean" test, as it could not obliterate all evidence of preexisting demyelination or nerve damage that the test would otherwise detect – and if it could actually do so in a few days' time after being administered, it would constitute an unheralded, miraculous cure for peripheral neuropathies. Rather, it is more likely that nerve damage beginning not long after Ms. Auch's October 6th vaccination (as consistent with Petitioner's allegations in this case), and severe enough to cause the degree of symptoms she claims, would be too extensive by more than a week later (especially given her reported symptoms of total limb dysfunction and numbness) to be masked by a one-time steroidal treatment.

C. Petitioner Has Not Demonstrated that the Flu Vaccine Caused Her 2010 Polyneuropathy.

Petitioner was never diagnosed with any form of neuropathy until August 2010 – ten months after the vaccination at issue. But no treaters at that time considered the flu vaccine to have played a role in Ms. Auch's condition. The medical record also reveals that Ms. Auch's complaints about her condition subsided for much of 2010, suggesting that (whatever their cause) the previous symptoms were no longer an issue – and thus does not help explain how her pain and related severe symptoms could have subsided from November 2009 until spontaneously flaring up long after. Nor did Dr. Steinman explain in a persuasive manner how Ms. Auch's medical history was consistent with the process he outlined, wherein the flu vaccine might cause a neuropathy, then become subacute for months on end before reappearing. The evidence does not preponderate in favor of the conclusion that Ms. Auch's 2010 diagnosed polyneuropathy is related to her reported October 2009 reactions.

My conclusion would be the same even if I found that Petitioner's October 2009 symptoms *were* vaccine-caused. As the medical record establishes, those symptoms largely abated less than two months from the date of vaccination. Several months thereafter passed without any complaint of pain or symptoms similar in character to those of October 2009. And by the time Ms. Auch was diagnosed with a polyneuropathy in August 2010, she did not relate the pain and symptoms to her earlier complaints – and the record also does not suggest they were so related by her treaters. Petitioner's experts did not otherwise persuasively link the October 2009 symptoms to those prompting Ms. Auch to seek treatment in August 2010.[26]

[26] Indeed, given the record in this case, even if I had found that Ms. Auch's October 2009 symptoms were vaccine-related, I would not be able to find as well that Petitioner has met the Vaccine Act's requirement of an injury lasting more than six months, since there is no evidence that her condition and complaints still existed as of April or May of

D. Petitioner's Proposed Timeframe for Development of Her Alleged Disease Was Dependent on the Finding that She had Experienced a Vaccine-Caused Neuropathy in 2009.

Had I found that Ms. Auch's symptoms beginning around a week after her October 6, 2009, vaccination constituted the onset of a polyneuropathy, then I would also be able to find that the timeframe in which it began was medically appropriate. Certainly a one-week timeframe for an autoimmune process of the kind proposed by Dr. Steinman is scientifically reasonable and reliable. *See, e.g.*, *D.S. v. Sec'y of Health & Human Servs.*, No. 10-077V, 2015 WL 8409472, at *25 (Fed. Cl. Spec. Mstr. May 19, 2015) (accepting the experts' opinions that an appropriate temporal period for the autoimmune process causing GBS to occur is one to six weeks); *Salmins v. Sec'y of Health & Human Servs.*, No. 11-140V, 2014 WL 1569478, at *18 (Fed. Cl. Spec. Mstr. Mar. 31, 2014) (one week after the triggering event for an autoimmune condition like GBS to occur was acceptable).

However, Ms. Auch's polyneuropathy was not diagnosed until almost a year later – and Petitioner did not successfully establish that her earlier symptoms were related to those she experienced the following summer. Nor did she establish that the flu vaccine could otherwise cause a neuropathic injury that would wax, wane, and then manifest acutely ten months after vaccination. She also failed to establish that her October 2009 symptoms were neuropathic, as alleged. As a result (and in particular due to Ms. Auch's inability to prove by preponderant evidence that the flu vaccine caused her to experience any neuropathy – as diagnosed in 2010, or as claimed without diagnosis in 2009), the reasonableness of the timeframe from a theoretical standpoint does not aid Petitioner given the facts of this case.

CONCLUSION

Petitioner and her family have unquestionably experienced tremendous difficulties in coping with her symptoms, and she persuasively established at trial the toll they have taken on her quality of life. But my sympathies for her suffering are an insufficient basis for an entitlement award. The Vaccine Act permits me to award compensation only if a petitioner alleging a "non-Table Injury," as here, can show by medical records or competent medical opinion that the claimed injury was more likely than not vaccine-caused. Petitioner's causation theory depends upon my

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2010. *See* Section 11(c)(1)(D)(i); *Song v. Sec'y of Health & Human Servs.*, No. 92-279, 1993 WL 534746, at *3 (Fed. Cl. Spec. Mstr. Dec. 15, 1993) (a petitioner bears the burden of proving by preponderant evidence that he suffered the residual effects or complications of a vaccine-related injury for longer than six months), *mot. for review den'd*, 31 Fed. Cl. 61 (1994), *aff'd,* 4 F.3d 1520 (Fed. Cir. 1994). The record better supports the conclusion that Petitioner's August 2010 diagnosis was unrelated to her earlier reported symptoms, whatever their initial cause; there is too much of a break in the records between the first set of symptoms from the fall of 2009 and those related to the polyneuropathy diagnosis to link the two.

finding that she experienced onset of a vaccine-induced neuropathy in 2009 that waned before being diagnosed almost a year later – but the weight of the evidence does not support that conclusion. Rather, the record facts suggest that any reaction she experienced after receipt of the flu vaccine was unrelated to her later diagnosis, and I do not find it more likely than not that her initial reactions and symptoms were the result of a vaccine. There is therefore insufficient evidence to support an award of compensation, leaving me no choice but to hereby **DISMISS** this claim.

In the absence of a timely-filed motion for review (see Appendix B to the Rules of the Court), the Clerk shall enter judgment in accord with this decision.[27]

IT IS SO ORDERED.

/s/ Brian H. Corcoran
Brian H. Corcoran
Special Master

[27] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing their right to seek review.